K113071

JAN - 9 2012

1.0 SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS [510(k) Summary] per the requirements 21 CFR 807.92

Date Prepared	January 03, 2012
Submitter	SYNTHES 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Andrea M. Tasker tasker.andrea@synthes.com phone: (610) 719-6920
Trade Name	SyntheCel® Dura Replacement Devices, SyntheCel® Dura Onlay, SyntheCel® Dura Substitute
Common Name	Dura Replacement Device
Classification Name	Dura Substitute
Classification	21 CFR 882.5910
Device Class	II
Review Panel	Neurology
Product Code(s)	GXQ
Predicate Devices	Bio-Vascular's Dura-Guard (K950956, K973706,K982282) Integra Lifescience's DuraGen (K982180) Gore - Preclude MVP (K021477)
Device Description	SyntheCel® Dura Replacement Devices (Onlay and Substitute) are composed of biosynthesized cellulose and water with a unique construction of non-woven, interconnected cellulose fibers. SyntheCel® Dura Replacement Devices function as a mechanical layer which protects and repairs the dural defect while preventing further CSF leakage. SyntheCel® Dura Replacement Devices are immunologically inert and have demonstrated minimal foreign body response. They are non-resorbable.
Intended Use	SyntheCel® Dura Replacement Devices are intended for use as a dura replacement for the repair of dura mater. SyntheCel® Dura Onlay is indicated for use in adults for the repair of dural defects and it can be placed without sutures. SyntheCel® Dura Substitute is indicated for use in adults for the repair of dural defects and it can be sutured into place.

K113071

Technological Characteristics	The SyntheCel® Dura Replacement Devices are similar to the three predicate devices (Bio-Vascular-Dura-Guard, Integra Lifesciences-DuraGen, and Gore-Preclude MVP) in terms of intended use. All three are intended for dura replacement for the repair of dura mater. The SyntheCel® Dura Replacement Devices are similar to the two predicate devices (Bio-Vascular-Dura-Guard, Integra Lifesciences-DuraGen) in terms of physical properties (form, size, physical integrity, thickness, suturability, drapability, conformability). The SyntheCel® Dura Replacement Devices are similar to the predicate device (Gore-Preclude MVP) in terms of resorbability. Both are non-resorbable.
Clinical Testing Data	Clinical data were collected to evaluate the safety and effectiveness of the SyntheCel® Dura Replacement Devices as compared to the Control. The objective of this study was to demonstrate that the SyntheCel® Dura Replacement Devices are substantially equivalent to other dura replacement products that were previously cleared for marketing by FDA. A total of 99 patients were enrolled, randomized and treated (62 in the investigational SyntheCel® treatment group and 37 in the control group) at 8 clinical sites. Patients were evaluated intra-operatively and immediately post-operatively (1 – 10 days) followed by evaluations at one (1) month, three (3) months and six (6) months. Complications and adverse events, device-related or not, were evaluated over the course of the clinical trial. At each evaluation time-point, the primary and secondary clinical outcome parameters were evaluated. Safety and effectiveness was assessed in all randomized subjects. Primary Efficacy Endpoint: The primary endpoint was based on the findings up to and including the 6 month follow-up visit. An individual patient's treatment was considered successful if and only if the following criterion was met: Success was defined as absence of CSF fistula (drainage from wound or sinus) and pseudomeningocele within 6 months post-operatively confirmed by radiographic evaluation and physical examination of surgical site. The results of overall success analyses indicate that the SyntheCel® is non-inferior to the dura replacement control group.

K113071

Non-Clinical Testing Data	Mechanical testing was performed for tensile strength, burst strength, and suture pull-out strength on samples of SyntheCel® Dura Replacement Devices and the predicates, DuraGen and Dura-Guard. All samples were prepared per respective instructions. SyntheCel® Dura Replacement Device performance was found to be comparable in tensile strength, burst strength, and suture pull-out strength. An animal study was performed comparing the SyntheCel® Dura Replacement Devices and predicate devices in a Rabbit Durotomy Implant Study. The results noted at necropsy show no meningitis, CSF leakage, evidence of infection, hydrocephalus, device vascularization, nor significant hemorrhage in any of the animals regardless of the implant type. Overall, the SyntheCel® Dura Substitute performed no different than the other predicate dura substitute materials. An additional Rabbit Durotomy Implant Study Model was performed using SyntheCel® Dura Replacement Devices. This study was conducted by NAMSA following GLPs. According to the conclusion, the SyntheCel® Dura Replacement Devices showed no evidence of a toxic leachable or local adverse effect. Biocompatibility testing according to standards set forth in ISO 10993 demonstrated that the material is non-irritating, non-sensitizing, non-mutagenic, non-cytotoxic, non-hemolytic, and non-pyrogenic. Pyrogenicity was evaluated using the Limulus Amebocyte Lysate (LAL) test on the final sterilized SyntheCel® device and found to be less than 0.06 EU/ml (Endotoxin Units / ml) per *FDA's Guidance Document for Dura Substitute Devices*. All SyntheCel® Dura Replacement Device lots will be tested to ensure they are less than 0.06 EU/ml and will be labeled non-pyrogenic.
Substantial Equivalence to Predicate Devices	Based on the information presented in this submission, which includes mechanical testing, pre-clinical testing, animal testing, and clinical testing, the SyntheCel® Dura Replacement Devices do not raise new questions of safety and effectiveness. Therefore, it can be concluded that the SyntheCel® Dura Replacement Devices are substantially equivalent to the predicate devices for dura replacement devices in commercial distribution for use as a dura replacement for the repair of dura mater.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 9 2012

Synthes
c/o Ms. Andrea M. Tasker
CMF Regulatory Affairs Manager, Synthes
1301 Goshen Parkway
West Chester, PA 19380

Re: K113071
Trade/Device Name: SyntheCel® Dura Replacement Devices
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: October 14, 2011
Received: October 18, 2011

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SYNTHES®

Indications for Use

510(k) Number (if known): K113071

Device Name: SyntheCel® Dura Replacement Devices

Indications For Use:

SyntheCel® Dura Replacement Devices are intended for use as a dura replacement for the repair of dura mater. SyntheCel® Dura Onlay is indicated for use in adults for the repair of dural defects and it can be placed without sutures. SyntheCel® Dura Substitute is indicated for use in adults for the repair of dural defects and it can be sutured into place.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of ~~CDRH, Office of Device~~ Evaluation (ODE)

~~Division~~ Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113071